

Application No. 10/589862  
Response to the Office Action dated December 16, 2008

### REMARKS

Favorable reconsideration of this application is requested in view of the following remarks.

Claim 1 has been amended to include the limitations of the previously presented claim 2. Claim 2 has been amended to include a lower limit as supported by the specification at page 4, lines 7-8. Claims 9 and 11 have been amended editorially.

Claims 1, 4-11, and 13-17 have been rejected under U.S.C. 102(b) as being anticipated by Foukes et al. (U.S. Patent No. 5,498,783). Applicants respectfully traverse this rejection.

The limitations of previously presented claim 2 have been included in claim 1. Foukes discloses a method of coating a substrate by two coating compositions, at least one of which includes a reactive acrylic copolymer in an amount of 1-20 % (see coln. 2, lines 35-52). Foukes, however, fails to disclose use of about 20-90 % of the methacrylate copolymer as claim 1 requires. Further, Foukes discloses that the copolymers are prepared by using conventional techniques (coln. 5, lines 64-67) and does not mention any absence of the alkalizing agent. As discussed for the Mehra reference below, the alkalizing agent has been used to neutralize the carboxyl groups in copolymers of the coating composition and improve properties of anti-coalescence, stability, and tackiness of the coating, and the copolymer of Foukes includes carboxyl groups (see abstract). Thus, there is no reasonable basis to assume that the product of Foukes is free from the alkalizing agent as claim 1 requires.

Accordingly, claim 1 is distinguished from Foukes, and this rejection should be withdrawn.

Amended claim 2 includes 30-90 % of the methacrylate copolymer, and further is distinguished from Foukes.

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Claims 1-17 have been rejected under 35 U.S.C. 102(b) as being anticipated by Mehra et al. (U.S. Patent No. 5,733,575). Applicants respectfully traverse this rejection.

Mehra discloses a non-toxic edible enteric film coating dry powder composition including an alkalinizing agent as an anti-coalescing and stabilizing agent or an agent reducing tackiness of the coating (see abstract and coln. 4, lines 3-7). Thus, Mehra fails to disclose that the enteric film coating composition includes no alkalinizing agent as claim 1 requires. For pharmaceuticals, it is beneficial to reduce a number of chemicals other than an active ingredient that are included in the pharmaceuticals from a safety perspective as well as an economical, because chemicals may have some toxicity even if it is low (see toxicity data of the material safety data sheet (MSDS) of tri-sodium phosphate at pages 4-5 attached hereto). Particularly, an alkalinizing agent such as tri-sodium phosphate, which Mehra discloses as a preferable alkalinizing agent (see coln. 3, line 64 – coln. 4, line 2), is hazardous for workers who manufacture the pharmaceuticals, and it is beneficial for pharmaceutical companies and their workers to exclude the alkalinizing agent from compositions of pharmaceuticals (see Health Effects in the MSDS at pages 2-3). By neutralizing carboxyl groups of the polymers with the alkalinizing agent, the conventional enteric film coating becomes acid-resistant, for example, in a stomach, and stable during a long-term storage, and reduces tackiness (see coln. 4, lines 6-7 of Mehra and page 2, lines 9-14 under “Summary of the Invention” and page 3, lines 3-6 of the specification). However, the enteric film coating composition of claim 1 obtains the properties of acid resistance, no tackiness, no coalescence, and long stability without including the alkalinizing agent (see page 3, lines 1-2, page 6, lines 1-3 under a list of coating process parameters, and page 6, last 3 lines – page 7, line 4 of the specification), and such properties would not have been expected in an enteric film coating composition excluding the alkalinizing agent. Accordingly, claim 1 is distinguished from Mehra, and this rejection should be withdrawn.

Claims 1-17 have been rejected under 35 U.S.C. 102(b) as being anticipated by Lech et al. (U.S. Patent No. 5,641,513). Applicants respectfully traverse this rejection.

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Lech discloses a method for coating pharmaceutical tablets (see abstract). Lech further discloses copolymers that have no carboxyl groups such as methacrylic amino ester copolymer as well as cellulose ethers such as hydroxypropyl methylcellulose and hydroxypropylmethylcellulose and polyethylene glycols (coln. 4, lines 26-39). The polymers that Lech discloses have no carboxyl groups to be neutralized by an alkalinizing agent and are different from methacrylate copolymer as claim 1 requires. In particular, methacrylic amino ester copolymer that Lech discloses is an ester, i.e., the copolymer has no free carboxyl group, and includes amino group, which is not acidic but basic if not substituted. In addition, among methacrylate copolymers, the methacrylate copolymer of Type C, which claim 1 requires, is a special type of methacrylate copolymer and is different from Type A and Type B (see the MSDS of Types A-C as attached hereto for the Examiner's convenience). Lech, however, also fails to disclose Type C methacrylate copolymer as claim 1 requires.

Moreover, the polymer coating ingredients of Lech are combined with saccharide, and the mixture is melted by heat and spun (see coln. 5, lines 19-24). Lech further discloses that by combining the polymer coating ingredient with saccharide, dispersion of the coating ingredients in water is promoted and that the ingredients are dissolved in water for less than 3 minutes and usually 20 seconds (see abstract, coln. 5, line 66-cola. 6, line 3, and coln. 6, lines 41-46). Even though Lech discloses enteric coatings in the Background section, this merely is part of a listing of coating examples for pharmaceutical tablets in the prior art (see coln. 1, lines 17-25). Lech fails to disclose that the coating composition of their invention itself is an enteric coating composition as claim 1 requires, and the nature of the method disclosed by Lech suggests that the coating would be rapid release, not delayed release. Thus, Lech fails to disclose the enteric film coating composition as claim 1 requires.

Accordingly, claim 1 is distinguished from Lech, and this rejection should be withdrawn.

Application No. 10/589862  
Response to the Office Action dated December 16, 2008

In view of the above, Applicants request reconsideration of the application in the form of a Notice of Allowance.



Dated: March 18, 2009

DPM/my/ad

Respectfully submitted,

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By: 

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## Material Safety Data Sheet

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USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

### METHACRYLIC ACID COPOLYMER, TYPE A

Catalog Number: 1396400

Revision Date: April 29, 2005

#### SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Methacrylic Acid Copolymer, Type A

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

Mailing Address: 12601 Twinbrook Parkway, Rockville, MD 20852 USA

Phone: 301-816-8129

Hours: 8 a.m. to 5 p.m. EST Mon. - Fri.

Product Use: USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

#### SECTION 2 - HAZARD INFORMATION

Adverse Effects: Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: n/f

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic: Possible hypersensitization.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material.

Cross Sensitivity: n/f

Target Organs: n/f

For additional information on toxicity, see Section 11.

#### SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Common Name: Methacrylic Acid Copolymer, Type A

Formula:  $(C_5H_8O_2)_x(C_4H_6O_2)_y$

Synonym: Acrylic copolymer

Chemical Name: Methacrylic Acid Copolymer, Type A

CAS: 25086-15-1

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n/f = not found

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**METHACRYLIC ACID COPOLYMER, TYPE A**

Catalog Number: 1396400

Revision Date:

April 29, 2005

RTECS Number: n/f

Chemical Family: Acrylic resin

Therapeutic Category: Pharmaceutical aid (tablet coating agent)

Composition: Pure Material

**SECTION 4 - FIRST AID MEASURES****Inhalation:** May cause irritation. Remove to fresh air.**Eye:** May cause irritation. Flush with copious quantities of water.**Skin:** May cause irritation. Flush with copious quantities of water.**Ingestion:** May cause irritation. Flush out mouth with water.**General First Aid Procedures:** Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.**Note to Physicians****Overdose Treatment:** For current information about the treatment of overdose, consult a certified Regional Poison Control Center by calling the number listed in your local telephone directory.**SECTION 5 - FIREFIGHTING MEASURES****Extinguisher Media:** Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.**Fire and Explosion Hazards:** This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.**Firefighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.**SECTION 6 - ACCIDENTAL RELEASE MEASURES****Spill Response:** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.**SECTION 7 - HANDLING AND STORAGE****Handling:** As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.**Storage:** Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.**SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION****Engineering Controls:** Engineering controls such as exhaust ventilation are recommended.**Respiratory Protection:** Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.**Gloves:** Chemically compatible**Eye Protection:** Safety glasses or goggles**Protective Clothing:** Protect exposed skin.**Exposure Limits:** n/f**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

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**METHACRYLIC ACID COPOLYMER, TYPE A**

Catalog Number: 1396400

Revision Date:

April 29, 2005

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Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

Appearance and Odor: White powder; weak to sour odor.

Odor Threshold: n/f

pH: n/f

Melting Range: n/f

Boiling Point: n/f

Flash Point: >482° F (COC)

Autoignition Temperature: >400° C

Evaporation Rate: >1 (butyl acetate = 1)

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: >1

Specific Gravity: n/f

Solubility in Water: Insoluble

Fat Solubility: n/f

Other Solubility: n/f

Partition Coefficient: n-octanol/water: n/f

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula:  $(C_5H_8O_2)_x, (C_4H_6O_2)_y$

Molecular Weight: Approximately 135,000

**METHACRYLIC ACID COPOLYMER, TYPE A**

Catalog Number: 1396400

Revision Date:

April 29, 2005

**SECTION 10 - STABILITY AND REACTIVITY**

Conditions to Avoid: Avoid heat.

Incompatibilities: n/f

Decomposition Products: When heated to decomposition material emits acrid smoke and irritating fumes. Emits toxic fumes under fire conditions.

Stable? Yes      Hazardous Polymerization? No

**SECTION 11 - TOXICOLOGICAL PROPERTIES**

Oral Rat: LD50: &gt;5000 mg/kg

Oral Mouse: LD50: n/f

Other Toxicity Data: n/f

Irritancy Data: n/f

Corrosivity: n/f

Sensitization Data: n/f

Listed as a Carcinogen by:      NTP: No      IARC: No      OSHA: No

Other Carcinogenicity Data: n/f

Mutagenicity Data: n/f

Reproductive and Developmental Effects: n/f

**SECTION 12 - ECOLOGICAL INFORMATION**

Ecological Information: n/f

**SECTION 13 - DISPOSAL CONSIDERATIONS**

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

**SECTION 14 - TRANSPORT INFORMATION**

Shipping Name: n/f

Class: n/f

UN Number: n/f

Packing Group: n/f

Additional Transport Information: n/f

**SECTION 15 - REGULATORY INFORMATION**

U.S. Regulatory Information: n/f

International Regulatory Information: n/f

**SECTION 16 - OTHER INFORMATION**

Revision:              29-Apr-05

Previous Revision Date:              21-Nov-01



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### METHACRYLIC ACID COPOLYMER, TYPE B

Catalog Number: 1396502

Revision Date:

October 23, 2007

#### SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

**Common Name:** Methacrylic Acid Copolymer, Type B

**Manufacturer:** U. S. Pharmacopeia

**Responsible Party:** Reference Standards Technical Services

**Mailing Address:** 12601 Twinbrook Parkway, Rockville, MD 20852 USA

**Phone:** 301-816-8129

**Hours:** 8 a.m. to 5 p.m. EST Mon. - Fri.

**Product Use:** USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

#### SECTION 2 - HAZARD INFORMATION

**Adverse Effects:** Possible allergic reaction to material if inhaled, ingested or in contact with skin.

**Overdose Effects:** n/f

**Acute:** Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

**Chronic:** Possible hypersensitization.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to material.

**Cross Sensitivity:** n/f

**Target Organs:** n/f

**For additional information on toxicity, see Section 11.**

#### SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

**Common Name:** Methacrylic Acid Copolymer, Type B

**Formula:** (C<sub>5</sub>H<sub>8</sub>O<sub>2</sub>)<sub>x</sub>, (C<sub>4</sub>H<sub>6</sub>O<sub>2</sub>)<sub>y</sub>

**Synonym:** Acrylic copolymer

**Chemical Name:** Methacrylic Acid Copolymer, Type B

**CAS:** 25086-15-1

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**METHACRYLIC ACID COPOLYMER, TYPE B**

Catalog Number: 1396502

Revision Date:

October 23, 2007

RTECS Number: n/f

Chemical Family: Acrylic resin

Therapeutic Category: Pharmaceutic aid (tablet coating agent)

Composition: Pure Material

**SECTION 4 - FIRST AID MEASURES****Inhalation:** May cause irritation. Remove to fresh air.**Eye:** May cause irritation. Flush with copious quantities of water.**Skin:** May cause irritation. Flush with copious quantities of water.**Ingestion:** May cause irritation. Flush out mouth with water.**General First Aid Procedures:** Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.**Note to Physicians****Overdose Treatment:** For current information about the treatment of overdose, consult a certified Regional Poison Control Center by calling the number listed in your local telephone directory.**SECTION 5 - FIREFIGHTING MEASURES****Extinguisher Media:** Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.**Fire and Explosion Hazards:** This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.**Firefighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.**SECTION 6 - ACCIDENTAL RELEASE MEASURES****Spill Response:** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.**SECTION 7 - HANDLING AND STORAGE****Handling:** As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.**Storage:** Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.**SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION****Engineering Controls:** Engineering controls such as exhaust ventilation are recommended.**Respiratory Protection:** Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.**Gloves:** Chemically compatible**Eye Protection:** Safety glasses or goggles**Protective Clothing:** Protect exposed skin.**Exposure Limits:** n/f**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

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**METHACRYLIC ACID COPOLYMER, TYPE B**

Catalog Number: 1396502

Revision Date:

October 23, 2007

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Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

Appearance and Odor: White powder; weak to sour odor.

Odor Threshold: n/f

pH: n/f

Melting Range: n/f

Boiling Point: n/f

Flash Point: >482° F (COC)

Autoignition Temperature: n/f

Evaporation Rate: >1 (butyl acetate = 1)

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: >1 (Air=1)

Specific Gravity: n/f

Solubility in Water: Practically insoluble

Fat Solubility: n/f

Other Solubility: Soluble in methanol and in ethanol; practically insoluble in ethyl acetate, in methylene chloride, and in petroleum ether

Partition Coefficient: n-octanol/water: n/f

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula:  $(C_5H_8O_2)_x, (C_4H_6O_2)_y$

Molecular Weight: Approximately 135,000

**METHACRYLIC ACID COPOLYMER, TYPE B**

Catalog Number: 1396502

Revision Date:

October 23, 2007

**SECTION 10 - STABILITY AND REACTIVITY**

Conditions to Avoid: Avoid heat.

Incompatibilities: n/f

Decomposition Products: When heated to decomposition material emits acrid smoke and irritating fumes. Emits toxic fumes under fire conditions.

Stable? Yes      Hazardous Polymerization? No

**SECTION 11 - TOXICOLOGICAL PROPERTIES**

Oral Rat: LD50: &gt;5000 mg/kg

Oral Mouse: LD50: n/f

Other Toxicity Data: Oral Dog: LD50: &gt;10 grams/kg

Irritancy Data: n/f

Corrosivity: n/f

Sensitization Data: n/f

Listed as a Carcinogen by:      NTP: No      IARC: No      OSHA: No

Other Carcinogenicity Data: n/f

Mutagenicity Data: n/f

Reproductive and Developmental Effects: n/f

**SECTION 12 - ECOLOGICAL INFORMATION**

Ecological Information: n/f

**SECTION 13 - DISPOSAL CONSIDERATIONS**

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

**SECTION 14 - TRANSPORT INFORMATION**

Shipping Name: n/f

Class: n/f

UN Number: n/f

Packing Group: n/f

Additional Transport Information: n/f

**SECTION 15 - REGULATORY INFORMATION**

U.S. Regulatory Information: n/f

International Regulatory Information: n/f

**SECTION 16 - OTHER INFORMATION**

Revision: 23-Oct-07

Previous Revision Date: 29-Apr-05



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## METHACRYLIC ACID COPOLYMER, TYPE C

Catalog Number: 1396604

Revision Date: April 29, 2005

### SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Methacrylic Acid Copolymer, Type C

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

Mailing Address: 12601 Twinbrook Parkway, Rockville, MD 20852 USA

Phone: 301-816-8129

Hours: 8 a.m. to 5 p.m. EST Mon. - Fri.

Product Use: USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

### SECTION 2 - HAZARD INFORMATION

Adverse Effects: Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: n/f

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic: Possible hypersensitization.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material.

Cross Sensitivity: n/f

Target Organs: n/f

For additional information on toxicity, see Section 11.

### SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Common Name: Methacrylic Acid Copolymer, Type C

Formula: n/f

Synonym: Acrylic copolymer

Chemical Name: Methacrylic Acid Copolymer, Type C

CAS: 25086-15-1

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n/f = not found

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**METHACRYLIC ACID COPOLYMER, TYPE C**

Catalog Number: 1396604

Revision Date:

April 29, 2005

RTECS Number: n/f

Chemical Family: Acrylic resin

Therapeutic Category: Pharmaceutic aid (tablet coating agent)

Composition: Pure Material

**SECTION 4 - FIRST AID MEASURES****Inhalation:** May cause irritation. Remove to fresh air.**Eye:** May cause irritation. Flush with copious quantities of water.**Skin:** May cause irritation. Flush with copious quantities of water.**Ingestion:** May cause irritation. Flush out mouth with water.**General First Aid Procedures:** Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.**Note to Physicians****Overdose Treatment:** For current information about the treatment of overdose, consult a certified Regional Poison Control Center by calling the number listed in your local telephone directory.**SECTION 5 - FIREFIGHTING MEASURES****Extinguisher Media:** Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.**Fire and Explosion Hazards:** This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.**Firefighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.**SECTION 6 - ACCIDENTAL RELEASE MEASURES****Spill Response:** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.**SECTION 7 - HANDLING AND STORAGE****Handling:** As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.**Storage:** Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.**SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION****Engineering Controls:** Engineering controls such as exhaust ventilation are recommended.**Respiratory Protection:** Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.**Gloves:** Chemically compatible**Eye Protection:** Safety glasses or goggles**Protective Clothing:** Protect exposed skin.**Exposure Limits:** n/f**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

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**METHACRYLIC ACID COPOLYMER, TYPE C**

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Catalog Number: 1396604

Revision Date: April 29, 2005

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Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

Appearance and Odor: White powder; faint to sour odor.

Odor Threshold: n/f

pH: n/f

Melting Range: n/f

Boiling Point: n/f

Flash Point: >250° C (COC)

Autoignition Temperature: >400° C

Evaporation Rate: >1 (butyl acetate = 1)

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: >1

Specific Gravity: n/f

Solubility in Water: Insoluble

Fat Solubility: n/f

Other Solubility: Soluble in aqueous alkalies, in acetone, and in lower alcohols.

Partition Coefficient: n-octanol/water: n/f

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula: n/f

Molecular Weight: Approximately 135,000

**METHACRYLIC ACID COPOLYMER, TYPE C**

Catalog Number: 1396604

Revision Date:

April 29, 2005

**SECTION 10 - STABILITY AND REACTIVITY**

Conditions to Avoid: n/f

Incompatibilities: n/f

Decomposition Products: When heated to decomposition material emits acrid smoke and irritating fumes. Emits toxic fumes under fire conditions.

Stable? Yes      Hazardous Polymerization? No

**SECTION 11 - TOXICOLOGICAL PROPERTIES**

Oral Rat: LD50: &gt;5000 mg/kg

Oral Mouse: LD50: n/f

Other Toxicity Data: Oral dog: LD50: &gt;5000 mg/kg

Irritancy Data: n/f

Corrosivity: n/f

Sensitization Data: n/f

Listed as a Carcinogen by:      NTP: No      IARC: No      OSHA: No

Other Carcinogenicity Data: n/f

Mutagenicity Data: n/f

Reproductive and Developmental Effects: n/f

**SECTION 12 - ECOLOGICAL INFORMATION**

Ecological Information: n/f

**SECTION 13 - DISPOSAL CONSIDERATIONS**

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

**SECTION 14 - TRANSPORT INFORMATION**

Shipping Name: n/f

Class: n/f

UN Number: n/f

Packing Group: n/f

Additional Transport Information: n/f

**SECTION 15 - REGULATORY INFORMATION**

U.S. Regulatory Information: n/f

International Regulatory Information: n/f

**SECTION 16 - OTHER INFORMATION**

Revision: 29-Apr-05

Previous Revision Date: 21-Nov-01



## MSDS TRISODIUM PHOSPHATE

Page 1 of 5

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**Postal Address:**

P.O Box 118, Newport

Victoria 3015

AUSTRALIA

**Telephone: 61/3/9250-1000****TRISODIUM PHOSPHATE****ISSUED: JUNE 15, 2000****Hazardous according to criteria of Worksafe  
Australia.****IDENTIFICATION**

**TRADE NAME :** Trisodium Phosphate  
**OTHER NAME :** Trisodium Phosphate Dodecahydrate; Sodium Phosphate Tribasic.  
**U.N. NO. :** None Allocated  
**DG CLASS :** None Allocated  
**PACKAGING GP. :** None Allocated  
**HAZCHEM :** None Allocated  
**POISON SCHEDULE :** Schedule 5  
**USES :** Detergents, Stain remover, cleaning.

**PHYSICAL DESCRIPTION/ PROPERTIES****Appearance, odour :** White crystalline powder, odourless**Melting Point :** Loses water above 100°C to give residue, which melts above 1000°C.**Boiling Point :** No data available<http://users.bigpond.net.au/tuscany/deltrex/products/s241.htm>

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**Vapour Pressure (20°C) :** No data available

**Density :** 1.6g/cm<sup>3</sup>

**Flash Point (Open Cup) :** Not applicable

**Explosion Limits :** Not applicable

**Solubility in Water :** 20g per 100 g @20°C

**OTHER PROPERTIES**

**pH :** 12.1 (10g/L solution @20°C)

**Molecular Formula :** Na<sub>3</sub>PO<sub>4</sub>·12H<sub>2</sub>O

**Molecular Weight :** 380.12

**Stability and reactivity :** Stable under normal temperatures and pressures. Incompatible with strong acids, strong bases, strong oxidising agents, strong reducing agents. Avoid high temperatures and dust generation.

**INGREDIENTS**

Chemical Name CAS Number Proportion

Trisodium phosphate Dodecahydrate 10101-89-0 >99%

**HEALTH HAZARD INFORMATION****HEALTH EFFECTS****ACUTE EFFECTS**

**SWALLOWED:** Product is highly alkaline and may cause severe damage to digestive tract. May cause burns and irritate mucous membrane.

**EYE:** Irritant to eyes. May cause eye burns and corneal damage.

**SKIN:** Dust is irritant to skin due to high alkalinity. Can cause skin sensitisation.

**INHALED:** Dust is irritating to the respiratory tract. May cause coughing, wheezing, shortness of breath and pulmonary edema.

**CHRONIC EFFECTS**

Repeated or prolonged contact especially under wet conditions may cause eye and skin inflammation.

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**FIRST AID**

**SWALLOWED:** IF conscious, immediately rinse mouth with water & give water to drink. Do not induce vomiting. Seek immediate medical assistance.

**EYE:** Immediately irrigate with copious quantities of water for at least 15 minutes. Eyelids to be held open. Seek immediate medical assistance.

**SKIN:** Remove contaminated clothing. Wash affected area with large amounts of soap and water. Seek medical assistance if irritation persists.

**INHALED:** Remove victim from exposure - avoid becoming a casualty. Remove contaminated clothing and loosen remaining clothing. Allow patient to assume most comfortable position and keep warm. Keep at rest until fully recovered. If breathing laboured ensure airways are clear and administer oxygen. If breathing has stopped apply artificial respiration at once. Seek immediate medical assistance.

**ADVICE TO DOCTOR**

Treat symptomatically.

**PRECAUTIONS FOR USE****EXPOSURE STANDARDS**

No value assigned by Worksafe Australia.

**Due to irritant effects on mucous membranes the following dust exposure limit should be enforced:**

**TWA:** <10mg/m<sup>3</sup>

TWA is the Time-Weighted Average airborne concentration over an 8-hour working day, for a 5-day working week over an entire working life.

**ENGINEERING CONTROLS**

Provide general and/or local exhaust ventilation system. Maintain exposures below the recommended exposure standard.

**PERSONAL PROTECTION**

Avoid skin and eye contact and inhalation of dust. Wear overalls, safety glasses or goggles and chemical resistant gloves and boots. Respiratory protection is required if airborne concentration exceeds exposure standards. Use an approved dust particle mask. Always wash hands before smoking, eating, drinking or using the toilet.

**FLAMMABILITY**

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Not flammable.

**SAFE HANDLING INFORMATION**

RECEIVED  
CENTRAL FAX CENTER  
MAR 18 2009

**STORAGE AND TRANSPORT**

Not classified as a dangerous Good by the Australian Code for the Transport of Dangerous Goods by Road and Rail. Store in a cool, dry, well ventilated place. Keep containers tightly sealed to prevent contact with moisture, which will cause the product to cake. Keep away from incompatible materials and foodstuffs. Protect from physical damage.

**SPILLS**

Wear proper protective equipment. Sweep up but avoid generating dust. Avoid contact with acids. Transfer spilled material into clean-labelled sealable containers for disposal.

Prevent from entering drains, sewers, streams or other bodies of water. If contamination of sewers or waterways has occurred, advise the local emergency services.

**DISPOSAL**

Refer to federal, state or local regulations.

**FIRE/EXPLOSION HAZARDS**

Non combustible material.

Extinguishing media is governed by other materials present. In the event of a fire, the material will generate toxic and irritating fumes. For this reason fire fighters to wear self contained breathing apparatus and full protective clothing when fighting fire.

**OTHER INFORMATION****TOXICITY****ACUTE TOXICITY:**

ORAL LD50 (rat): 7400 mg/kg

**ENVIRONMENTAL IMPACT**

No specific data available but high concentrations in receiving waters will harm aquatic life by raising pH. The orthophosphate can act as a plant nutrient and precipitate heavy metals.

**Hazard Category:** Irritant

**Risk Statement:** R36/37/38 Irritating to eyes, respiratory system and skin.

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**Safety Statement:** S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S28 After contact with skin, wash immediately with plenty of soap-suds.

**CONTACT POINT**

**Phone: (03) 9250 1000**

**Phone: 1 800 628 724 (24hr - Emergency Contact)**

**This MSDS has been prepared from current technical data and summarises at the date of issue our best knowledge of the health and safety information of the product, and in particular how to safely handle and use the product in the workplace. Each user should read this MSDS and consider the information in the context of how the product will be handled and used in the workplace.**

**If clarification or further information is needed to ensure that an appropriate assessment can be made, the user should contact this company.**

**Our responsibility for products sold is subject to our standard terms and conditions, a copy of which is sent to our customers and is also available upon request**

**END OF MSDS NO 241**